

### **REMARKS**

In an office action dated January 28, 2004, claims 85-99 have been rejected under 35 U.S.C. §101, §112, second paragraph, and §102(b). In response, Applicants have amended claims 85-99 and provide the herein remarks. Claims 85-99 are pending in the application.

### **The Invention**

The invention is directed to peptides that are derived from a protein called "lipopolysaccharide binding protein (LBP)," and modified. The claimed peptides are of restricted length, from 14 to 22 amino acid residues, and have unnatural modifications.

The claimed peptides are identical to SEQ ID NO:1 except that SEQ ID NO:1 has undergone one of the amino acid substitutions defined in (i) through (iv) of claim 85. Also, the modified SEQ ID NO:1 peptide can optionally have an extension of up to 4 amino acid residues at each end of the peptide.

SEQ ID NO: 1 contains 14 amino acid residues, namely, Arg Val Gln Gly Arg Trp Lys Val Arg Lys Ser Phe Phe Lys. This sequence occurs naturally, not as a peptide, but as part of LBP.

The present invention does not claim SEQ ID NO:1, or peptides containing the same. Instead, the present invention claims peptides that differ from SEQ ID NO: 1 by one amino acid substitution, and optionally, by extensions of up to 4 amino acid residues at either end of the sequence.

Applicants have discovered that the claimed substitutions to SEQ ID NO:1 confer vigorous LPS-binding and neutralizing activity to the peptides of the invention.

### **Rejection Under 35 U.S.C. §101**

In the office action, claims 85-99 have been rejected under §101 as being directed to non-statutory matter because the claims recite a peptide which allegedly reads on products of nature.

In response, Applicants have amended the claims to recite "A purified peptide..." Accordingly, Applicants respectfully submit that the rejection under §101 has been overcome and should be withdrawn.

### **Rejection Under 35 U.S.C. §112, First Paragraph**

Claims 85-99 have been rejected under §112, second paragraph, as allegedly being indefinite. In particular, the Examiner contends that in claim 85 it is unclear as to which portion of SEQ ID NO: 1 the peptide is derived from.

In response, Applicants have added language to claim 85 to clarify that the claimed peptide is derived from SEQ ID NO: 1 by modification of one amino acid residue. The modification is further defined as "an amino acid substitution selected from the group consisting of..."

The Examiner contends that the phrase "backbone-mimetic organic entities" in claim 93 is not defined by the claim or in the specification. The phrase "backbone-mimetic organic entities" is a term of art that refers to compounds wherein the amide peptide of the peptide has been replaced by, for example, sugar rings, steroids, benzodiazepines, or other hetero- and carbocycles.

Claim 93 has been rejected for lacking antecedent basis for the phrase "the chain backbone." The peptide amide chain backbone refers to the repetitive structural element of

all peptides -NH-CH-CO-. When speaking about a peptide, one may refer to the chain backbone without the need of an antecedent basis therefore, as it is inherent to any peptide that it comprises a backbone.

In response, Applicants have amended claim 93 to remove the word "chain" from the claim in a sincere effort to clarify what is meant by "the backbone."

Claim 98 has been rejected as depending on a cancelled claim. In response, Applicants have amended claim 98 to depend on claim 85.

Claims 86-88, 990-92, 94-97 and 99 have been rejected for depending on claim 85, which has been deemed indefinite. In response, as mentioned above, Applicants have amended claim 85 to no longer be indefinite.

Accordingly, in light of the above amendments and remarks, Applicants respectfully request that the rejections under §112, second paragraph, be reconsidered and withdrawn.

#### **Rejections Under 35 U.S.C. §102(b)**

In the office action, claims 85-88, 91 and 96 have been rejected under §102(b) as being anticipated by U.S. Patent No. 5,731,415 to Gazzano-Santoro et al. ('415 patent).

According to the Examiner, the '415 patent teaches a LPS binding protein derived from SEQ ID NO:1, and therefore, anticipates the claimed invention. Applicants respectfully disagree.

The '415 patent discloses peptides containing a part of the lipopolysaccharide binding protein (LBP). Some of the disclosed peptides contain SEQ ID NO:1. The '415 patent does not disclose or suggest any peptides that represent substitution modifications of SEQ ID NO:1. Moreover, the '415 patent does not disclose the claimed substitution modifications of SEQ ID NO:1.

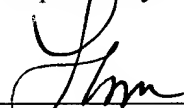
In stark contrast, the present invention is restricted to peptides containing one of various substitution modifications of SEQ ID NO:1. See the discussion above and claim 85. Peptides containing (or consisting of) SEQ ID NO:1 itself are not claimed.

The selected substitutions represented in claim 85 confer vigorous LPS-binding and neutralizing activity to the peptide molecules of the claimed invention. For illustration, Example 1 of the application demonstrates the vigorous LPS-binding properties of the claimed peptides. Examples 2-4 demonstrate the vigorous LPS-neutralizing properties of the claimed peptides.

Therefore, since the '415 patent does not disclose the claimed peptides, it can not be found to anticipate the claimed invention. Accordingly, Applicants respectfully request that the rejection under §102(b) be reconsidered and withdrawn.

In light of the foregoing remarks, Applicants respectfully submit that the application is now in condition for allowance. If Examiner Shannon-Shah believes a telephone discussion with the Applicants' representative would be of assistance, he is invited to contact the undersigned at his convenience.

Respectfully submitted,



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